

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

BOEHRINGER TECHNOLOGIES, LLC;  
BOEHRINGER LABORATORIES, INC.;  
and  
BOEHRINGER LABORATORIES, LLC

Plaintiffs,

v.

TOOLS FOR SURGERY, LLC

Defendant.

Docket No. \_\_\_\_\_

JURY TRIAL DEMANDED

**COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF**

For their complaint against Defendant, Tools for Surgery, LLC (“Defendant” or “Tools for Surgery”), Plaintiffs Boehringer Technologies, LLC (individually “Plaintiff” or “Boehringer Technologies”), Boehringer Laboratories, Inc. (individually “Plaintiff” or “Boehringer Laboratories, Inc.”), and Boehringer Laboratories, LLC (individually “Plaintiff” or “Boehringer Laboratories, LLC”) (collectively “Plaintiffs” or “Boehringer”) state:

**SUMMARY OF CASE**

1. This is an action for damages and injunctive relief to remedy the infringement by Defendant of Plaintiffs’ U.S. Patents Nos. 9,808,368 (the “‘368 Patent”), 9,999,533 (the “‘533 Patent”), 10,888,446 (the “‘446 Patent”), 10,932,937 (the “‘937 Patent”), 11,511,030 (the “‘030 Patent”), and 12,303,415 (the “‘415 Patent”). The patents are attached as Exhibits 1-6, respectively. Collectively, the ‘368, ‘533, ‘446, ‘937, ‘030, and ‘415 patents are the “Patents.”
2. The Patents are directed to gastric sizing and bariatric surgical instruments.

**JURISDICTION AND PARTIES**

3. Boehringer Technologies, LLC is a Pennsylvania limited liability company with its principal place of business at 300 Thoms Dr., Phoenixville, PA.
4. Boehringer Technologies is the owner of each of the Patents.
5. Boehringer Technologies, LLC was, prior to conversion on or about December 31, 2022, formerly known as Boehringer Technologies, L.P.
6. Boehringer Laboratories, LLC is a Pennsylvania limited liability company with its principal place of business at 300 Thoms Dr., Phoenixville, PA.
7. Boehringer Laboratories, LLC sells and offers for sale authorized products under one or more of the Patents.
8. Boehringer Laboratories, Inc. is a Pennsylvania corporation with its principal place of business at 300 Thoms Dr., Phoenixville, PA.
9. Boehringer Laboratories, Inc. is the parent company of Boehringer Laboratories, LLC and Boehringer Technologies.
10. Upon information and belief, Tools for Surgery, LLC is a New York Limited Liability Company with its principal place of business at 8 Technology Drive, Suite 100, East Setauket, NY, 11733.
11. This Court has subject matter jurisdiction over the Plaintiffs' patent infringement claims under 28 U.S.C. § 1331 and § 1338 because it arises under federal law.
12. This Court has personal jurisdiction over Tools for Surgery because, on information and belief, it does business and has offered for sale and sold the accused devices in the Eastern District of Pennsylvania.

13. Venue is proper in this Court under 28 U.S.C. § 1400 because Plaintiffs reside in this district and have a principal place of business in this district and their agents reside in this district. On information and belief, Defendant has committed acts of infringement in this district. That is, Defendant sells and offers to sell products in this district and, on information and belief, by selling the accused devices in this district.

**DEFENDANT’S INFRINGEMENT OF THE PATENTS**

14. Defendant is making, using and selling infringing products in the United States that (a) are covered by (a) one or more of the claims without limitation of the Patents. The devices of Defendant entitled Siren SGT Orogastric Tubes and/or the ZZIREN SGT Orogastric tubes for bariatric and gastric surgery infringe the claims of the Patents. On information and belief, the Siren SGT Orogastric Tubes and /or the ZZIREN SGT Tubes for bariatric and gastric surgery are being sold in Pennsylvania.
15. Upon information and belief, the Defendant has been aware of the Patents since at least as early as December 24, 2018, when an attorney for Arnold Leiboff, President of Defendant, filed an information disclosure statement with the United States Patent and Trademark Office in the prosecution of U.S. patent application serial number 16/231,713 for “Method for Maintaining Suction in Body Cavities,” which identified Leiboff as the inventor and owner (and which would later become U.S. Patent No. 11,006,957 [Leiboff]) identifying U.S. patent publication number 2014/0148732 (Radl), which had become The ‘368 Patent on November 7, 2017, and U.S. patent publication number 2014/0148731 (Radl), which had become The ‘533 Patent on June 19, 2018.
16. Upon information and belief, the Defendant was aware of the Patents on December 8, 2020, when the United States Patent and Trademark Office cited U.S. patent publication

number 2014/0148732 (Radl), which had become The ‘368 Patent on November 7, 2017, as the primary reference to reject Leiboff’s claims in the patent application for “Method for Maintaining Suction in Body Cavities.”

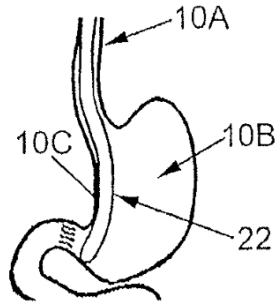
17. Further, Defendant was given 510(k) premarket approval by the FDA for its Siren SGT™ Gastrointestinal Tube and Accessories on May 18, 2022, which the Defendant’s January 19, 2022, 510(k) application based upon its Substantial Equivalence Comparison of the Defendant’s Siren SGT with Plaintiffs’ ViSiGi® 3D device which incorporates the inventions of the Patents. That is, it was the fact that Defendant’s Siren SGT is substantially equivalent to Plaintiffs’ ViSiGi® 3D device that Plaintiffs’ device was permitted to be marketed in the United States. Similarly, on January 10, 2025, Defendant was given 510(k) premarket approval by the FDA for its ZZIREN SGT Orogastric Tube device for the same reason, it was found to be a substantial equivalent of the Plaintiffs’ ViSiGi® 3D device that had been permitted to be marketed in the United States.
18. Recently Defendant’s Siren SGT and/or ZZIREN versions of an orogastric tube for bariatric surgery began to be marketed by Defendant even though, on information and belief, Defendant knew, or should have known, it was infringing Plaintiffs’ Patents.

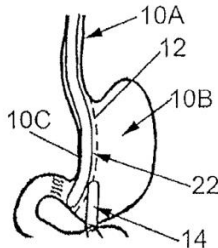
**COUNT ONE**  
**INFRINGEMENT OF THE ‘368 PATENT**

19. The Plaintiffs incorporate by reference all allegations in all preceding paragraphs of this complaint as if fully rewritten herein.
20. Defendant has directly infringed, and continues to directly infringe, the ‘368 Patent at least by selling, offering to sell, using, and/or making Infringing Products.
21. Defendant’s Siren SGT and/or ZZIREN instruments infringe at least Claim 1 of the ‘368 Patent. That is, the Siren SGT and/or ZZIREN instruments not only are substantially

equivalent but also have all of the elements claimed by Plaintiffs' Patents. The infringing Siren SGT and the ZZIREN Orogastric Tubes are for all material elements referenced the same. Accordingly, the Claims are compared below with the information relative to the Siren SGT device which is the same as the ZZIREN device for all material purposes. Thus, each of the Defendant's instruments have the elements of Claim 1 of the '368 Patent as illustrated below with respect to the Siren SGT device:

| <b>Claim 1 (U.S. Pat. 9,808,368)</b>  | <b>Siren SGT Device</b>   |
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| A method of sizing the stomach of a patient for a bariatric procedure, the stomach of the patient having a lesser curvature and a greater curvature, said method comprising   | See the highlighted Siren SGT Orogastric Tube instructions for use (attached as Exhibit A) which states "The SIREN SGT is indicated for use in gastric and bariatric surgical procedures . . . and to assist in gastric sleeve formation by decompressing the stomach and serving as a sizing guide." Also see the highlighted Siren SGT Orogastric Tube For Bariatric and Gastric Surgery (attached as Exhibit B). Also see the highlighted FDA U.S. Food & Drug Administration letter dated May 18, 2022, to Tools For Surgery, LLC finding substantial equivalence of the SIREN SGT device to the ViSiGi® 3D device (attached as Exhibit C) sold by Boehringer Laboratories, LLC, the owner of the subject patent. The Boehringer ViSiGi® 3D device is covered by the subject patent. Also see U.S. Patent 11,006,957 of Arnold Leiboff (attached as Exhibit D). Also attached as Exhibit E is a highlighted FDA U.S. Food & Drug Administration letter dated Jan. 10, 2025, to Tools For Surgery, LLC finding substantial equivalence of the ZZIREN SGT Orogastric Tube device to the prior SIREN SGT device, which itself was deemed substantially equivalent to the Boehringer ViSiGi® 3D device. Thus, this claim chart also covers the ZZIREN SGT Orogastric Tube devices which are described in Exhibit F. |
| providing a non-expandable instrument for introduction into the stomach of the patient,   | The Siren SGT device includes an elongate insertion tube which is formed of a flexible material that is not expandable.   |
| said instrument comprising a sizing tube in the form of an elongated tubular member having a longitudinal axis extending along a length thereof, a hollow interior, a distal end portion and a proximal end portion, said distal end portion having a plurality of apertures disposed around the periphery of said sizing tube, | The insertion tube acts as a sizing tube. It is an elongated member as can be seen in Exhibits A, B, C and D and inherently has a longitudinal axis. Moreover, it has a hollow interior (a lumen 111 identified in Exhibit D), a blunt distal tip with a smooth surface and multiple side holes (apertures) disposed about the periphery of the sizing tube   |

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|  | adjacent the distal end, as shown in Exhibits A, B and C.   |
| said plurality of apertures extending along said longitudinal axis and with said apertures directed in a plurality of different radial directions from said longitudinal axis, said plurality of apertures being in fluid communication with said hollow interior of said elongated tubular member;  | The holes (apertures) are disposed along a distal portion of the longitudinal axis and extend in a plurality of directions, e.g., at 90 degrees to each other around the periphery of the insertion tube as shown clearly in Exhibits A and B. The holes are in fluid communication with the lumen 111 of Exhibit D.  |
| introducing said sizing tube into the stomach of the patient in any orientation about said longitudinal axis so that said elongated tubular member extends along the majority of the lesser curvature of the patient's stomach and directly engages the lesser curvature of the patient's stomach,   | <p>The Siren SGT device is substantially equivalent to the ViSiGi® 3D device as set forth in Exhibit C and is used in this manner for the formation of a gastric sleeve, e.g., a sleeve gastrectomy, where the insertion tube is extended along and engages the lesser curvature 10C of the patient's stomach like shown in Fig. 4 of the subject patent illustrated below.</p>  <p><b>Fig. 4</b></p> <p>See also Exhibit D ('957 Patent-Claim 3; col. 4, lines 44-45)</p> |
| whereupon plural ones of said plurality of apertures face towards the lesser curvature of the patient's stomach irrespective of the particular orientation of said sizing tube about said longitudinal axis in the patient's stomach and with said plural ones of said plurality of apertures that face towards the lesser curvature of the patient's stomach extending along the lesser curvature of the patient stomach; | Since the holes (apertures) in the insertion tube extend about the periphery of the distal end portion of the insertion tube at an angle of 90 degrees to each other, plural ones of the apertures will face the lesser curvature irrespective of the particular orientation of the insertion tube within the patient's stomach.  |
| connecting said sizing tube to a source of suction;  | The insertion tube includes an integral suction regulating valve to limit suction applied to the Siren SGT device from a source of suction (a vacuum source). See point "4" of the "Instructions For Use" portion of Exhibit A.   |
| applying controlled suction into the interior of the patient's stomach via (i) said plural ones of said plurality of apertures facing the lesser   | The suction applied is controlled as set forth clearly in point "4" of the "Instructions For Use" portion of  |

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| <p>curvature of the patient's stomach and (ii) others of said plurality of apertures facing away from the lesser curvature of the patient's stomach to pull the lesser curvature of the patient's stomach into engagement with the portion of said sizing tube facing the lesser curvature of the patient's stomach and</p>   | <p>Exhibit A with the side holes (apertures) of the insertion tube facing in the directions set forth.</p>  |
| <p>without any portion of said instrument engaging the greater curvature of the patient's stomach, and contemporaneously therewith said controlled suction applied via said others of said plurality of apertures pulls portions of the patient's stomach adjacent thereto towards portions of said sizing tube not facing the lesser curvature of the patient's stomach to anchor said sizing tube in place thereat in said any orientation about said longitudinal axis and</p> | <p>When positioned against the lesser curvature and suction applied to the insertion tube the suction anchors the insertion tube as set forth clearly in point "5" of the "Instructions For Use" portion of Exhibit A.</p>  |
| <p>without the use of any expandable member to hold said sizing tube in place and to produce a suction-created visually perceptible delineation line on the exterior of the patient's stomach along a portion of the periphery of said sizing tube facing the greater curvature of the patient's stomach;</p>   | <p>No other member, expandable or otherwise is used to hold the insertion tube in place and when in place with suction applied a visually perceptible delineation line is produced on the exterior of the patient's stomach along a portion of the periphery of insertion tube facing the greater curvature of the patient's stomach.</p>   |
| <p>visualizing said suction-created visually perceptible delineation line with a laparoscope from outside of the patient's stomach; and</p>   | <p>The Siren SGT device is substantially equivalent to the ViSiGi® 3D device as set forth in Exhibit C and is operated in the same manner as the Boehringer ViSiGi® 3D device. Fig. 5 of the subject patent reproduced below shows the delineation line 12 produced by the subject invention and the ViSiGi® 3D device. The same line is produced by the Siren SGT device</p>  <p>The diagram shows a cross-section of a stomach. An insertion tube, labeled 10A, enters the stomach at the top. A dashed line, labeled 12, runs along the lesser curvature of the stomach. Other labels include 10B, 10C, 22, and 14, which point to various parts of the stomach and the tube.</p> <p><b>Fig. 5</b></p> <p>See also Exhibit D ('957 Patent-Claim 5)</p> |

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| maintaining said controlled suction onto said portions of the patient's stomach while laparoscopically sealing the patient's stomach adjacent said visually perceptible delineation line from the outside of the patient's stomach to form a permanent seal line while said sizing tube is anchored in place by the controlled suction applied via said ones of said plurality of apertures and said others of said plurality of apertures. | The patient's stomach adjacent the visually perceptible delineation line is sealed, e.g., stapled, along the visually perceptible delineation line produced by the Siren SGT device. |
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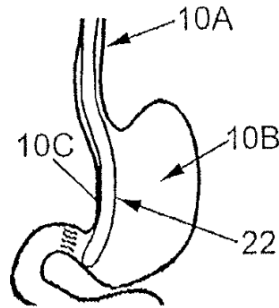
22. On information and belief Defendant or its customers are infringing the '368 Patent because the SIREN SGT product's intended use is for a method of sizing for a bariatric procedure, and any use of the Infringing Product as a method of sizing in a bariatric procedure is an act of contributory and/or direct infringement of the '368 Patent because the Infringing Product has no substantial non-infringing uses.
23. Defendant has induced infringement of the '368 Patent at least because, with knowledge of the '368 Patent, it intentionally and actively induced end users of the Infringing Product (through instructions, and otherwise) to use it in a manner that infringes the '368 Patent with specific intent that they do so.
24. Defendant has contributed to infringement of the '368 Patent at least by selling the Infringing Product, which has no substantial use other than an infringing use as a method of sizing for a bariatric procedure.
25. Defendant's infringements of the '368 Patent were, and continue to be, willful and deliberate.
26. The Plaintiffs have been damaged by Defendant's infringing activities, and they will continue to be irreparably injured unless the infringing activities are enjoined by this Court.



**COUNT TWO**  
**INFRINGEMENT OF THE ‘533 PATENT**

27. The Plaintiffs incorporate by reference all allegations in all preceding paragraphs of this complaint as if fully rewritten herein.
28. Defendant has directly infringed, and continues to directly infringe, the ‘533 Patent, at least by selling, offering to sell, using, and/or making Infringing Products.
29. Defendant’s Siren SGT and/or ZZIREN instruments infringe at least Claim 1 of the ‘533 Patent. That is, the Siren SGT and/or ZZIREN instruments not only are substantially equivalent but also have all of the elements claimed by Plaintiffs’ Patents. The infringing Siren SGT and the ZZIREN Orogastric Tubes are for all material elements referenced the same. Accordingly, the Claims are compared below with the information relative to the Siren SGT device which is the same as the ZZIREN device for all material purposes. Thus, each of the Defendant’s instruments have the elements of Claim 1 of the ‘533 Patent as illustrated below with respect to the Siren SGT device:

| <b>Claim 1 (U.S. Pat. 9,999,533)</b>  | <b>Siren SGT Device</b>   |
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| A system for sizing a patient's stomach for a bariatric procedure, the patient's stomach having a lesser curvature and a greater curvature, said system comprising: | See the highlighted Siren SGT Orogastric Tube instructions for use (attached as Exhibit A) which states “The SIREN SGT is indicated for use in gastric and bariatric surgical procedures . . . and to assist in gastric sleeve formation by decompressing the stomach and serving as a sizing guide.” Also see the highlighted Siren SGT Orogastric Tube For Bariatric and Gastric Surgery (attached as Exhibit B). Also see the highlighted FDA U.S. Food & Drug Administration letter dated May 18, 2022, to Tools For Surgery, LLC finding substantial equivalence of the SIREN SGT device to the ViSiGi® 3D device (attached as Exhibit C) sold by Boehringer Laboratories, LLC, the owner of the subject patent. The Boehringer VISIGI ® 3D device is covered by the subject patent. Also see U.S. Patent 11,006,957 of Arnold Leiboff (attached as Exhibit D). Also attached as Exhibit E is a highlighted FDA U.S. Food & Drug Administration letter dated Jan. 10, 2025, to Tools For Surgery, LLC finding substantial equivalence of |

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|  | the ZZIREN SGT Orogastric Tube device to the prior SIREN SGT device, which itself was deemed substantially equivalent to the Boehringer ViSiGi® 3D device. Thus, this claim chart also covers the ZZIREN SGT Orogastric Tube devices which are described in Exhibit F.  |
| a one-piece device configured for introduction through the esophagus into the patient's stomach so that it is resident by itself in the patient's stomach with a portion of said one-piece device disposed along the lesser curvature of the patient's stomach,  | <p>The Siren SGT device is substantially equivalent to the ViSiGi® 3D device as set forth in Exhibit C and is operated in the same manner as the Boehringer ViSiGi® 3D device. The Siren SGT device includes an elongate insertion tube which is a one-piece device disposed along the lesser curvature 10C of the patient's stomach in a similar manner as shown in Fig. 4 of the subject patent reproduced below.</p>  <p>Fig. 4</p> |
| said one-piece device consisting of a sizing tube, said sizing tube comprising:  | The elongate insertion tube constitutes the claimed sizing tube   |
| a distal free end; a proximal end portion; and   | The elongate insertion tube includes a distal free end (a blunt tip with a smooth surface as shown in Exhibit B. It also includes a proximal end portion  |
| an elongated unitary tubular member having a central longitudinal axis, a hollow interior extending about said central longitudinal axis,  | The elongate insertion tube inherently has a hollow interior (lumen 111 of Exhibit D) extending along a central longitudinal axis   |
| and a sidewall, said sidewall including a portion configured for extending the entire length of the lesser curvature of the patient's stomach and bent into a curved shape directly engaging the lesser curvature of the patient's stomach, said sidewall being formed of a flexible non-expandable material, whereupon said portion of said sidewall is always able to bend into said curved shape in close conformance with the lesser curvature of the patient's stomach, | The elongate insertion tube inherently has a sidewall. Inasmuch as the Siren SGT device is substantially equivalent to the ViSiGi® 3D device as set forth in Exhibit C it is formed of a flexible non-expandable material and is able to bend into a curved shape in close conformance with the lesser curvature 10C of the patient's stomach.  |
| said sidewall including a plurality of apertures extending through said sidewall, a group of said plurality of apertures being disposed in an array  | The Siren SGT includes a plurality of side holes (apertures) in an array extending through the sidewall disposed about the entire periphery of the sizing tube adjacent the distal end, as shown in Exhibits A and B.   |

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| extending about the entire periphery of said sidewall,   |  |
| whereupon adjacent ones of said apertures of said array are spaced from each other by an angle greater than zero degrees measured about said central longitudinal axis and extend in more than two radial directions with respect to said central longitudinal axis,   | As best seen in Exhibits A and B the side holes extend about the periphery of the distal end portion of the insertion tube at an angle of 90 degrees to each other and hence extend in more than two radial directions with respect to the longitudinal axis.  |
| said array extending from a point adjacent said distal free end to an intermediate point located between said distal free end and said proximal end portion,   | The array extends from a point adjacent the distal end to an intermediate point as clearly shown in Figs. A, B and C   |
| said plurality of apertures being in fluid communication with said hollow interior of said sizing tube;  | The side holes are in fluid communication with the hollow interior (lumen 111 of Exhibit D)  |
| said one-piece device being configured to be coupled to a source of suction, whereupon controlled suction is applied to said hollow interior of said sizing tube and through said array to apply suction to the lesser curvature of the patient's stomach and portions of the patient's stomach between said one-piece device and the greater curvature of the patient's stomach to bring those portions of the patient's stomach into close engagement with the periphery of said one-piece device, | As set forth in Exhibits A and C the Siren SGT device is configured to be coupled to a vacuum source to apply controlled suction to the hollow interior of the insertion tube and through the array of side holes to apply suction to the patient's stomach. Moreover, the Siren SGT device being substantially equivalent to the ViSiGi® 3D device (as set forth in Exhibit D) when used brings the portions of the patient's stomach into close engagement with the periphery of the insertion tub |
| whereupon said one-piece device can be used as a guide to enable the patient's stomach to be sized therealong, said controlled suction as applied by said array serving as the sole means of holding said one-piece device in place in said curved shape against the lesser curvature of the patient's stomach.  | When in place the one-piece insertion tube acts as a sizing guide as set forth in Exhibit A and D. Moreover, the suction applied through the side holes is the sole means of holding the insertion tube in place.  |

30. On information and belief, Defendant or its customers are infringing the '533 Patent because the SIREN SGT product's intended use is for a method of sizing for a bariatric procedure, and any use of the Infringing Product as a method of sizing in a bariatric procedure is an act of contributory and/or direct infringement of the '533 Patent because the Infringing Product has no substantial non-infringing uses.
31. Defendant has induced infringement of the '533 Patent at least because, with knowledge of the '533 Patent, it intentionally and actively induced end users of the Infringing Product

(through instructions, and otherwise) to use it in a manner that infringes the ‘533 Patent with specific intent that they do so.

32. Defendant has contributed to infringement of the ‘533 Patent at least by selling the Infringing Product, which has no substantial use other than an infringing use as a method of sizing for a bariatric procedure.
33. Defendant’s infringements of the ‘533 Patent were, and continue to be, willful and deliberate.
34. The Plaintiffs have been damaged by Defendant’s infringing activities, and they will continue to be irreparably injured unless the infringing activities are enjoined by this Court.

**COUNT THREE  
INFRINGEMENT OF THE ‘446 PATENT**

35. The Plaintiffs incorporate by reference all allegations in all preceding paragraphs of this complaint as if fully rewritten herein.
36. Defendant has directly infringed, and continues to directly infringe, the ‘446 Patent at least by selling, offering to sell, using, and/or making Infringing Products.
37. Defendant’s Siren SGT and/or ZZIREN instruments infringe at least Claim 1 of the ‘446 Patent. That is, the Siren SGT and/or ZZIREN instruments not only are substantially equivalent but also have all of the elements claimed by Plaintiffs’ Patents. The infringing Siren SGT and the ZZIREN Orogastric Tubes are for all material elements referenced the same. Accordingly, the Claims are compared below with the information relative to the Siren SGT device which is the same as the ZZIREN device for all material purposes. Thus, each of the Defendant’s instruments have the elements of Claim 1 of the ‘446 Patent as illustrated below with respect to the Siren SGT device:

| <b>Claim 1 (U.S. Pat. 10,888,446)</b>  | <b>Siren SGT Device</b>  |
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| A system for sizing the stomach of a patient for a bariatric procedure, said system comprising:  | See the highlighted Siren SGT Orogastric Tube instructions for use (attached as Exhibit A) which states “The SIREN SGT is indicated for use in gastric and bariatric surgical procedures . . . and to assist in gastric sleeve formation by decompressing the stomach and serving as a sizing guide.” Also see the highlighted Siren SGT Orogastric Tube For Bariatric and Gastric Surgery (attached as Exhibit B). Also see the highlighted FDA U.S. Food & Drug Administration letter dated May 18, 2022, to Tools For Surgery, LLC, finding substantial equivalence of the SIREN SGT device to the ViSiGi® 3D device (attached as Exhibit C) sold by Boehringer Laboratories, LLC, the owner of the subject patent. The Boehringer ViSiGi® 3D device is covered by the subject patent. Also see U.S. Patent 11,006,957 of Arnold Leiboff (attached as Exhibit D). Also attached as Exhibit E is a highlighted FDA U.S. Food & Drug Administration letter dated Jan. 10, 2025, to Tools For Surgery, LLC finding substantial equivalence of the ZZIREN SGT Orogastric Tube device to the prior SIREN SGT device, which itself was deemed substantially equivalent to the Boehringer ViSiGi® 3D device. Thus, this claim chart also covers the ZZIREN SGT Orogastric Tube devices which are described in Exhibit F. |
| a suction controller configured for producing controlled suction from a source of suction;   | Exhibits A and B clearly show that the Siren SGT device includes a suction controller for connection to a source of suction (a vacuum source).   |
| a non-expandable instrument configured to be coupled to said suction controller, said instrument being a single elongated member forming a sizing tube formed of a flexible non-expandable material having a predetermined outside diameter configured for introduction through the esophagus into the stomach of the patient so that a portion of said sizing tube is disposed along the lesser curvature of the patient's stomach, | The Siren SGT device is substantially equivalent to the ViSiGi® 3D device as set forth in Exhibit C and is operated in the same manner as the Boehringer ViSiGi® 3D device. The Siren SGT device includes an elongate insertion tube which is a non-expandable and configured to be coupled to the suction controller. As best seen in Exhibits A and B the insertion tube has a predetermined outside diameter, e.g., 36 French. Points 2, 3 and 4 of the Instructions For Use portion of Exhibit A describe the positioning of the insertion tube. For sizing the stomach, the insertion tube is disposed along the lesser curvature 10C of the patient's stomach as shown in Fig. 4 of subject patent reproduced below.   |

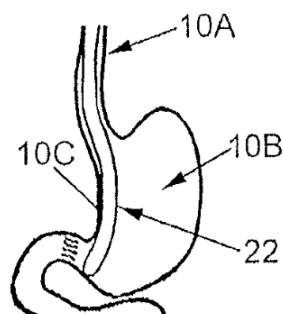
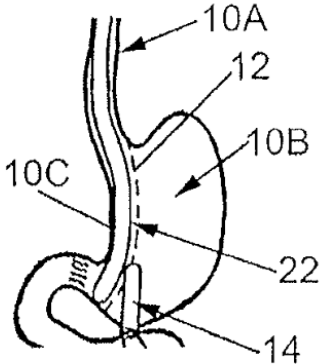


Fig. 4

See also Exhibit D ('957 Patent-Claim 3; col. 4, lines 44-45)

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| <p>said sizing tube having a longitudinal axis, a hollow interior defining a passageway, a proximal end portion, a tip having a distal end that is unencumbered, and a plurality of apertures disposed about the periphery of said distal end portion,</p>  | <p>The insertion tube inherently has a longitudinal axis. Moreover, it has a hollow interior defining a passageway (lumen 111 identified in Exhibit D), a distal end (tip) with a smooth surface and a plurality of side holes (apertures) disposed about the periphery of distal end portion, as shown in Exhibits A, B and C.</p>  |
| <p>said plurality of apertures being directed in a plurality of different radial directions from said longitudinal axis and being in fluid communication with said passageway,</p>  | <p>The side holes are in fluid communication with the lumen 111</p>  |
| <p>plural ones of said apertures extending along a portion of the lesser curvature of the patient's stomach when said sizing tube is located within the patient's stomach, whereupon controlled suction is applied to the hollow interior of said sizing tube and through said apertures to pull the lesser curvature of the patient's stomach into engagement with a portion of said sizing tube and contemporaneously therewith to pull other portions of the patient's stomach adjacent to said sizing tube towards portions of said sizing tube not facing the lesser curvature of the patient's stomach to anchor said sizing tube in place without the use of any expandable member to hold said sizing tube in place and</p> | <p>The side holes extend along the lesser curvature when the insertion tube is in place. The Siren SGT device is substantially equivalent to the ViSiGi® 3D device as set forth in Exhibit C AND operates in the same manner as the ViSiGi® 3D device when suction is applied to the side holes in the Siren SGT device to bring the lesser curvature of the patient's stomach into engagement with a portion of said sizing tube and contemporaneously therewith to pull other portions of the patient's stomach adjacent to said sizing tube towards portions of said sizing tube not facing the lesser curvature of the patient's stomach to anchor said sizing tube in place without the use of any expandable member to hold said sizing tube in place. See point "5" of the instructions for use portion of Exhibit A.</p> |
| <p>to produce a suction-created visually perceptible delineation line on the exterior of the patient's stomach along a portion of the periphery of said sizing tube facing the greater</p>  | <p>The Siren SGT device is substantially equivalent to the ViSiGi® 3D device as set forth in Exhibit C. The Siren SGT device is operated in the same manner as the Boehringer ViSiGi® 3D device. Fig. 5 of the subject</p>   |

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| <p>curvature of the patient's stomach to serve as a guide enabling the patient's stomach to be sized along said suction-created visually perceptible delineation line and</p>  | <p>patent reproduced below shows the delineation line 12 produced by the subject invention. The same line is produced by the Siren SGT device</p>  <p>Fig. 5</p> <p>See also Exhibit D ('957 Patent-Claim 5)</p>  |
| <p>with said controlled suction as applied by said apertures serving as the sole means anchoring said sizing tube in place;</p>  | <p>Nothing other than the suction applied by the side holes holds the insertion tube in place</p>   |
| <p>wherein said suction controller is configured to apply controlled suction to said hollow interior of said sizing tube to result in a force in a range of 0.05 to 200 pounds anchoring said sizing tube in position within the patient's stomach;</p>  | <p>The Siren SGT device is substantially equivalent to the ViSiGi® 3D device as set forth in Exhibit C. It is operated in the same manner as the ViSiGi® 3D device provides the force in the range of 0.05 to 200 pounds anchoring said sizing tube. Based on the identical number (144) and size (0.125" diameter) of the holes used in the Siren SGT device as compared to the ViSiGi® 3D device, the Siren Total Force per Model was calculated to fall with the 0.05-200lb range.</p> |
| <p>wherein said sizing tube is configured to apply a suction force per unit length within the patient's stomach at the location of said apertures when said controlled suction is applied to said sizing tube, whereupon the suction force applied per unit length is in a range of 0.02 to 21 pounds per inch based upon an aperture area of 1.2 square inches.</p> | <p>The Siren SGT device is substantially equivalent to the ViSiGi® 3D device as set forth in Exhibit C. It is operated in the same manner as the ViSiGi® 3D device. Based on the actual aperture area per inch, it was calculated that all force values per inch of the Siren SGT device are within the 0.02 to 21 pounds range.</p>  |

38. Defendant has contributed to infringement of the '446 Patent at least by selling the Infringing Product, which has no substantial use other than an infringing use as a method of sizing for a bariatric procedure. Defendant has induced infringement of the '446 Patent at least because, with knowledge of the '446 Patent, it intentionally and actively induced

end users of the Infringing Product (through instructions, and otherwise) to use it in a manner that infringes the '446 Patent with specific intent that they do so.

39. Defendant has contributed to infringement of the '446 Patent at least by selling the Infringing Product, which has no substantial use other than an infringing use as a method of sizing for a bariatric procedure.

40. Defendant's infringements of the '446 Patent were, and continue to be, willful and deliberate.

41. The Plaintiffs have been damaged by Defendant's infringing activities, and they will continue to be irreparably injured unless the infringing activities are enjoined by this Court.

#### **COUNT FOUR INFRINGEMENT OF THE '937 PATENT**

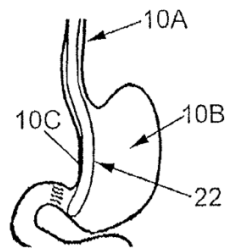
42. The Plaintiffs incorporate by reference all allegations in all preceding paragraphs of this complaint as if fully rewritten herein.

43. Defendant has directly infringed, and continues to directly infringe, the '937 Patent at least by selling, offering to sell, using, and/or making Infringing Products.

44. Defendant's Siren SGT and/or ZZIREN instruments infringe at least Claim 1 of the '937 Patent. That is, the Siren SGT and/or ZZIREN instruments not only are substantially equivalent but also have all of the elements claimed by Plaintiffs' Patents. The infringing Siren SGT and the ZZIREN Orogastric Tubes are for all material elements referenced the same. Accordingly, the Claims are compared below with the information relative to the Siren SGT device which is the same as the ZZIREN device for all material purposes. Thus, each of the Defendant's instruments have the elements of Claim 1 of the '937 Patent as illustrated below with respect to the Siren SGT device:



| <b>Claim 1 (U.S. Pat. 10,932,937)</b>   | <b>Siren SGT Device</b>  |
|---|--|
| A system for sizing a patient's stomach for a bariatric procedure, the patient's stomach having a lesser curvature and a greater curvature, said system comprising:   | See the highlighted Siren SGT Orogastric Tube instructions for use (attached as Exhibit A) which states “The SIREN SGT is indicated for use in gastric and bariatric surgical procedures . . . and to assist in gastric sleeve formation by decompressing the stomach and serving as a sizing guide.” Also see the highlighted Siren SGT Orogastric Tube For Bariatric and Gastric Surgery (attached as Exhibit B). Also see the highlighted FDA U.S. Food & Drug Administration letter dated May 18, 2022 to Tools For Surgery, LLC finding substantial equivalence of the SIREN SGT device to the ViSiGi® 3D device (attached as Exhibit C) sold by Boehringer Laboratories, LLC, the owner of the subject patent. The Boehringer ViSiGi® 3D device is covered by the subject patent. Also see U.S. Patent 11,006,957 of Arnold Leiboff (attached as Exhibit D). Also attached as Exhibit E is a highlighted FDA U.S. Food & Drug Administration letter dated Jan. 10, 2025, to Tools For Surgery, LLC finding substantial equivalence of the ZZIREN SGT Orogastric Tube device to the prior SIREN SGT device, which itself was deemed substantially equivalent to the Boehringer ViSiGi® 3D device. Thus, this claim chart also covers the ZZIREN SGT Orogastric Tube devices which are described in Exhibit F. |
| a distal free end; a proximal end portion; and  | As clearly shown in Exhibits A and B the Siren SGT device includes a connector at its proximal end and an elongate insertion tube connected to the connector by a suction regulator and valve. The elongate insertion tube has a distal free end.  |
| an elongated tubular member having a central longitudinal axis, a hollow interior extending about said central longitudinal axis, and a sidewall,   | The elongate insertion tube inherently has a sidewall and a longitudinal axis. Moreover, it has a hollow interior (a lumen 111 identified in Exhibit D),   |
| said sidewall including a portion configured for extending the entire length of the lesser curvature of the patient's stomach and bent into a curved shape directly engaging the lesser curvature of the patient's stomach, | The Siren SGT device is substantially equivalent to the ViSiGi® 3D device as set forth in Exhibit C and is operated in the same manner as the Boehringer ViSiGi® 3D device, e.g., the insertion tube is extended along and engages the lesser curvature 10C of the patient's stomach like shown in Fig. 4 of the subject patent illustrated below.   |



**Fig. 4**

See also Exhibit D ('957 Patent-Claim 3; col. 4, lines 44-45)

|  |  |
|--|--|
| said sidewall being formed of a flexible non-expandable material, whereupon said portion of said sidewall is always able to bend into said curved shape to conform with the lesser curvature of the patient's stomach,   | The Siren SGT device includes an elongate insertion tube having a sidewall which is formed of a non-expandable flexible material able to conform to the lesser curvature of the patient's stomach.   |
| said sidewall including a plurality of apertures extending through said sidewall in an array extending about the entire periphery of said sidewall, whereupon, said array extending from a point adjacent said distal free end to an intermediate point located between said distal free end and said proximal end portion,  | The insertion tube includes a plurality of side holes (apertures) extending through the sidewall in an array disposed about the entire periphery of the insertion tube adjacent the distal end. Those holes extend in a plurality of directions, e.g., at 90 degrees to each other around the periphery of the insertion tube as shown clearly in Exhibits A and B.  |
| said plurality of apertures being in fluid communication with said hollow interior of said sizing tube;  | The holes are in fluid communication with the lumen 111 of Exhibit D.  |
| said sizing tube being configured to have controlled suction applied to said hollow interior of said sizing tube and through said array to apply suction to the lesser curvature of the patient's stomach and portions of the patient's stomach between said sizing tube and the greater curvature of the patient's stomach to bring those portions of the patient's stomach into close engagement with the periphery of said sizing tube, | Controlled suction is applied to the insertion tube as set forth clearly in point "4" of the "Instructions For Use" portion of Exhibit A with the holes (apertures) of the insertion tube facing in the directions set forth. When positioned against the lesser curvature and suction applied to the insertion tube as described in point "5" of the instructions for use the suction brings portions of the patient's stomach into close engagement with the periphery of the insertion tube |
| whereupon said sizing tube can be used as a guide to enable the patient's stomach to be sized therealong, with said controlled suction as applied by said array serving as the sole means of holding said sizing tube in place in said curved shape against the lesser curvature of the patient's stomach.   | Exhibit A clearly shows that the Siren SGT device serves as a sizing guide. Moreover, No other member, only suction, is used to hold the insertion tube in place. See also Exhibit D ('957 Patent-Claim 5)   |

45. Defendant has contributed to infringement of the ‘937 Patent at least by selling the Infringing Product, which has no substantial use other than an infringing use as a method of sizing for a bariatric procedure.
46. Defendant has induced infringement of the ‘937 Patent at least because, with knowledge of the ‘937 Patent, it intentionally and actively induced end users of the Infringing Product (through instructions, and otherwise) to use it in a manner that infringes the ‘937 Patent with specific intent that they do so.
47. Defendants’ infringements of the ‘937 Patent were, and continue to be, willful and deliberate.
48. The Plaintiffs have been damaged by Defendant’s infringing activities, and they will continue to be irreparably injured unless the infringing activities are enjoined by this Court.

**COUNT FIVE  
INFRINGEMENT OF THE ‘030 PATENT**

49. The Plaintiffs incorporate by reference all allegations in all preceding paragraphs of this complaint as if fully rewritten herein.
50. Defendant has directly infringed, and continues to directly infringe, the ‘030 Patent at least by selling, offering to sell, using, and/or making Infringing Products.
51. Defendant’s Siren SGT and/or ZZIREN instruments infringe at least Claim 1 of the ‘030 Patent. That is, the Siren SGT and/or ZZIREN instruments not only are substantially equivalent but also have all of the elements claimed by Plaintiffs’ Patents. The infringing Siren SGT and the ZZIREN Orogastric Tubes are for all material elements referenced the same. Accordingly, the Claims are compared below with the information relative to the Siren SGT device which is the same as the ZZIREN device for all material purposes. Thus,

each of the Defendant's instruments have the elements of Claim 1 of the '030 Patent as illustrated below with respect to the Siren SGT device:

| <b>Claim 1 (U.S. Pat. 11,511,030)</b>   | <b>Siren SGT Device</b>  |
|---|--|
| A one-piece, unitary device for use in a system including a suction controller for sizing the stomach of a patient for a bariatric procedure, the stomach of the patient having a lesser curvature and a greater curvature, said device comprising:                                 | See the highlighted Siren SGT Orogastic Tube instructions for use (attached as Exhibit A) which states "The SIREN SGT is indicated for use in gastric and bariatric surgical procedures . . . and to assist in gastric sleeve formation by decompressing the stomach and serving as a sizing guide." Also see the highlighted Siren SGT Orogastic Tube For Bariatric and Gastric Surgery (attached as Exhibit B). Also see the highlighted FDA U.S. Food & Drug Administration letter dated May 18, 2022 to Tools For Surgery, LLC finding substantial equivalence of the SIREN SGT device to the ViSiGi® 3D device (attached as Exhibit C) sold by Boehringer Laboratories, LLC, the owner of the subject patent. The Boehringer ViSiGi® 3D device is covered by the subject patent. Also see U.S. Patent 11,006,957 of Arnold Leiboff (attached as Exhibit D). Also attached as Exhibit E is a highlighted FDA U.S. Food & Drug Administration letter dated Jan. 10, 2025, to Tools For Surgery, LLC finding substantial equivalence of the ZZIREN SGT Orogastic Tube device to the prior SIREN SGT device, which itself was deemed substantially equivalent to the Boehringer ViSiGi® 3D device. Thus, this claim chart also covers the ZZIREN SGT Orogastic Tube devices which are described in Exhibit F. |
| an elongated sizing tube composed of a flexible polymer,  | The Siren SGT device includes an elongate insertion tube (a sizing tube) which is formed of a flexible material (Exhibit A)  |
| said elongated sizing tube being a one-piece unitary member having a cylindrical sidewall including an interior surface defining a single longitudinally extending passageway, said single longitudinally extending passageway being empty,   | The insertion tube is a one-piece unitary tubular member which inherently has a sidewall and a hollow interior passageway (lumen 111 identified in Exhibit D) which is empty.  |
| said cylindrical sidewall having a longitudinal axis extending along the length thereof, a distal end portion, a proximal portion, an exterior periphery, a free end tip, and a plurality of apertures in fluid communication with said single longitudinally extending passageway, | The insertion tube inherently has a longitudinal axis, a distal end portion and a proximal portion. The insertion tube has an exterior periphery and a free end tip (a blunt tip with a smooth surface). All of those features are shown in Exhibit B. Moreover, the insertion tube includes a plurality of side holes (apertures) which are in fluid communication with the lumen 111.  |
| said plurality of apertures extending along a portion of said longitudinal axis from a point  | The holes (apertures) are disposed along a distal portion of the longitudinal axis and extend in a plurality of  |

adjacent said free end tip, said free end tip forming a free end of said device, said plurality of apertures being located on more than two respective axes extending in a plurality of different radial directions outward from said longitudinal axis and around said exterior periphery,

said elongated sizing tube being configured for introduction into the patient's stomach so that a first portion of said exterior periphery extends along the lesser curvature of the stomach, with a second portion of the periphery extending towards the greater curvature of the patient's stomach, and with said free end tip being located within the patient's stomach,

directions, e.g., at 90 degrees to each other around the periphery of the insertion tube as shown clearly in Exhibits A and B. Thus, the side holes are located on more than two respective axes in a plurality of different radial directions.

The Siren SGT device is substantially equivalent to the ViSiGi® 3D device as set forth in Exhibit C and is used in the same manner as the ViSiGi® 3D device wherein a first peripheral portion of the sidewall of the insertion tube extends along the lesser curvature 10C of the patient's stomach and a second peripheral portion of the sidewall extends towards the greater curvature like shown in Fig. 4 of the subject patent illustrated below.

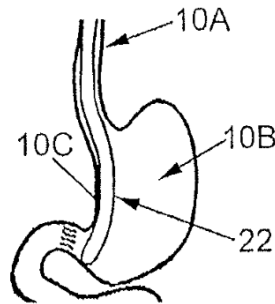
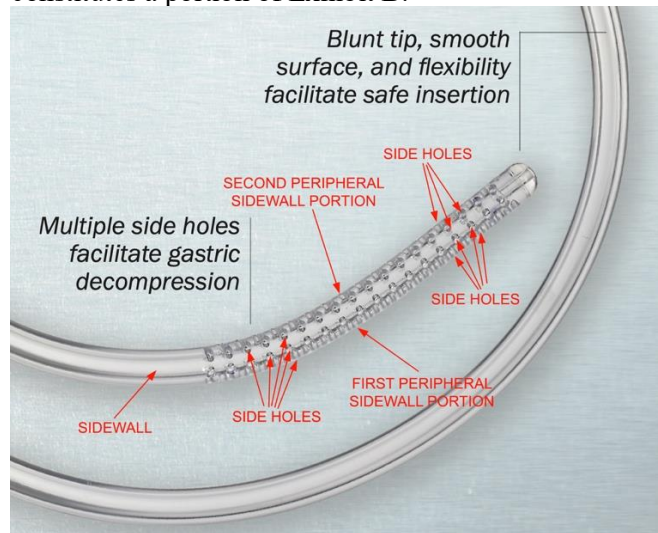
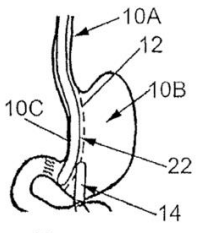
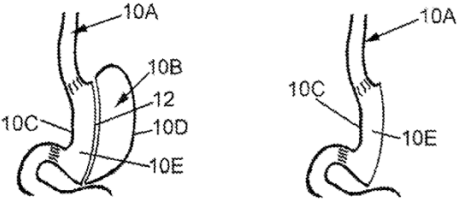


Fig. 4

The first and second peripheral sidewall portions are shown in the annotated photograph below which constitutes a portion of Exhibit B.



See also Exhibit D ('957 Patent-Claim 3; col. 4, lines 44-45)

|  |  |
|--|--|
| <p>said proximal portion of said elongated sizing tube being configured to be coupled to the suction controller for applying controlled suction to the interior of the patient's stomach via said plurality of apertures to pull a portion of the lesser curvature of the patient's stomach into direct engagement with said first portion of said periphery and to pull other portions of the patient's stomach adjacent to said second section into direct engagement with said second portion of said periphery to anchor said elongated sizing tube in place and</p> | <p>The insertion tube includes an integral suction regulating valve to limit suction applied to the Siren SGT device from a source of suction (a vacuum source). See point "4" of the "Instructions For Use" portion of Exhibit A. When positioned against the lesser curvature and suction applied to the insertion tube the suction is applied through the peripheral side holes pulls a portion of the lesser curvature of the stomach into direct engagement with the first peripheral portion of the sidewall of the insertion tube and pulls other portions of the patient's stomach adjacent the second peripheral portion of the sidewall into direct engagement with that portion of the sidewall to anchors the insertion tube in place. See point "5" of the "Instructions For Use" portion of Exhibit A.</p> |
| <p>to produce a suction-created visually perceptible delineation line on the exterior of the patient's stomach along said second section thereby enabling a portion of the patient's stomach adjacent the suction-created visually perceptible delineation line to be sealed by a device located outside the patient's stomach while said elongated sizing tube is anchored in place to form a sealed residual stomach portion about said elongated sizing tube.</p>   | <p>Fig. 5 of the subject patent reproduced below shows the delineation line 12 produced by the subject invention and the ViSiGi® 3D device. The same line is produced by the Siren SGT device</p>  <p><b>Fig. 5</b></p> <p>During use of the Siren SGT device for sizing the stomach a portion of the patient's stomach is sealed, e.g., stapled, along the delineation line to form a sealed residual stomach portion like shown in Figs. 6 and 7 of the subject patent reproduced below.</p>  <p><b>Fig. 6</b>      <b>Fig. 7</b></p> <p>See also Exhibit D ('957 Patent-Claim 5)</p>  |

52. Defendant has induced infringement of the '030 Patent at least because, with knowledge of the '030 Patent, it intentionally and actively induced end users of the Infringing Product

(through instructions, and otherwise) to use it in a manner that infringes the '030 Patent with specific intent that they do so.

53. Defendant has contributed to infringement of the '030 Patent at least by selling the Infringing Product, which has no substantial use other than an infringing use as a method of sizing for a bariatric procedure.
54. Defendant's infringements of the '030 Patent were, and continue to be, willful and deliberate.
55. The Plaintiffs have been damaged by Defendant's infringing activities, and they will continue to be irreparably injured unless the infringing activities are enjoined by this Court.

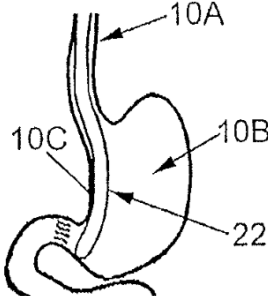
**COUNT SIX  
INFRINGEMENT OF THE '415 PATENT**

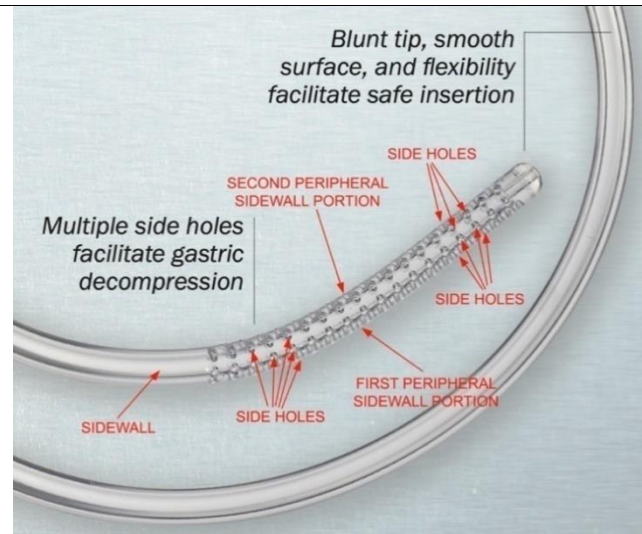
56. The Plaintiffs incorporate by reference all allegations in all preceding paragraphs of this complaint as if fully rewritten herein.
57. Defendant has directly infringed, and continues to directly infringe, the '415 Patent at least by selling, offering to sell, using, and/or making Infringing Products.
58. Defendant's Siren SGT and/or ZZIREN instruments infringe at least Claim 1 of the '415 Patent. That is, the Siren SGT and/or ZZIREN instruments not only are substantially equivalent but also have all of the elements claimed by Plaintiffs' Patents. The infringing Siren SGT and the ZZIREN Orogastric Tubes are for all material elements referenced the same. Accordingly, the Claims are compared below with the information relative to the Siren SGT device which is the same as the ZZIREN device for all material purposes. Thus, each of the Defendant's instruments have the elements of Claim 1 of the '415 Patent as illustrated below with respect to the Siren SGT device:



| <b>Claim 1 (U.S. Pat. 12,303,415)</b>   | <b>Siren SGT Device</b>  |
|---|--|
| A method of sizing a patient's stomach for a bariatric procedure, said method comprising:   | See the highlighted Siren SGT Orogastric Tube instructions for use (attached as Exhibit A) which states “The SIREN SGT is indicated for use in gastric and bariatric surgical procedures . . . and to assist in gastric sleeve formation by decompressing the stomach and serving as a sizing guide.” Also see the highlighted Siren SGT Orogastric Tube For Bariatric and Gastric Surgery (attached as Exhibit B). Also see the highlighted FDA U.S. Food & Drug Administration letter dated May 18, 2022 to Tools For Surgery, LLC finding substantial equivalence of the SIREN SGT device to the VISIGI 3D device (attached as Exhibit C) sold by Boehringer Laboratories, LLC, the owner of the subject patent. The Boehringer ViSiGi® 3D device is covered by the subject patent. Also see U.S. Patent 11,006,957 of Arnold Leiboff (attached as Exhibit D, including Claims 3 and 5 thereof). Also attached as Exhibit E is a highlighted FDA U.S. Food & Drug Administration letter dated Jan. 10, 2025, to Tools For Surgery, LLC finding substantial equivalence of the ZZIREN SGT Orogastric Tube device to the prior SIREN SGT device, which itself was deemed substantially equivalent to the Boehringer ViSiGi® 3D device. Thus, this claim chart also covers the ZZIREN SGT Orogastric Tube devices. which are described in Exhibit F. |
| a) introducing a non-expandable instrument comprising a sizing tube comprising a single member into the stomach of the patient through the patient's esophagus so that a portion of said sizing tube is disposed along the lesser curvature of the patient's stomach,   | The Siren SGT device includes a single elongate insertion tube (a sizing tube) which is not expandable (Exhibit A) and has a portion of the sizing tube disposed along the lesser curvature of the patient's stomach Claim 3 (Exhibit D)   |
| said sizing tube comprising an elongated member having a longitudinal axis and a circular cross-section having a circular outer surface, whereupon when said sizing tube is disposed along the lesser curvature of the patient's stomach the circular outer surface of said sizing tube is exposed for engagement by portions of the patient's stomach, | The insertion tube is an elongated tubular member inherently has a longitudinal axis and a circular cross-section with a circular outer surface this is exposed for engagement by portions of the patient's stomach (Exhibits A and D)   |
| a hollow interior defining a passageway, a distal end portion and a proximal end portion, said distal end portion terminating in a free end tip, said distal end portion having a predetermined outside diameter and a plurality of apertures   | The insertion tube has a passageway, a distal end portion and a proximal portion. The insertion tube has a free end tip (a blunt tip with a smooth surface). Moreover, there are a plurality of apertures disposed about the circular outer surface of the distal end  |



|  |  |
|--|--|
| disposed about said circular outer surface of said distal end portion,   | portion. All of those features are shown in Exhibits A and B.  |
| said plurality of apertures being directed in a plurality of different radial directions from said longitudinal axis and being in fluid communication with said passageway, said circular outer surface being entirely continuous along an entire length of said sizing tube between said apertures;   | The holes (apertures) are directed in a plurality of different radial directions from a longitudinal axis (Exhibits A and B) and are in fluid communication with the passageway of the lumen 111 (Exhibit D). The circular outer surface is entirely continuous along an entire length of the sizing tube between the apertures. See Exhibits A and B.   |
| b) connecting said passageway of said sizing tube to a source of controlled suction whereupon controlled suction is applied to the interior of the patient's stomach via said plurality of apertures to pull the lesser curvature of the patient's stomach into engagement with a portion of said sizing tube without any portion of said instrument being interposed between said entirely continuous circular outer surface of said sizing tube and the interior of the patient's stomach, and | <p>The insertion tube includes an integral suction regulating valve to limit suction applied to the Siren SGT device from a source of suction (a vacuum source). See point "4" of the "Instructions For Use" portion of Exhibit A. The Siren SGT device is substantially equivalent to the ViSiGi® 3D device as set forth in Exhibit C and is used in the same manner as the ViSiGi® 3D device wherein a first peripheral portion of the sidewall of the insertion tube extends along the lesser curvature 10C of the patient's stomach and a second peripheral portion of the sidewall extends towards the greater curvature like shown in Fig. 4 of the subject patent illustrated below.</p>  <p><b>Fig. 4</b></p> <p>The first and second peripheral sidewall portions are shown in the annotated photograph below which constitutes a portion of Exhibit B.</p> |



A controlled suction is applied through the plurality of apertures without any portion of the Siren SGT device being interposed between the entirely continuous circular outer surface of the sizing tube and the interior of the patient. See also Exhibit D ('957 Patent-Claim 3; col. 4, lines 44-45)

to produce a suction-created visually perceptible delineation line on the exterior of the patient's stomach along a portion of said entirely continuous circular outer surface of said sizing tube facing the greater curvature of the patient's stomach; and

The insertion tube includes an integral suction regulating valve to limit suction applied to the Siren SGT device from a source of suction (a vacuum source). See point "4" of the "Instructions For Use" portion of Exhibit A. When positioned against the lesser curvature and suction applied to the insertion tube the suction is applied through the peripheral side holes pulls a portion of the lesser curvature of the stomach into direct engagement with the first peripheral portion of the sidewall of the insertion tube and pulls other portions of the patient's stomach adjacent the second peripheral portion of the sidewall into direct engagement with that portion of the sidewall to anchors the insertion tube in place. See point "5" of the "Instructions For Use" portion of Exhibit A. Fig. 5 of the subject patent reproduced below shows the delineation line 12 produced by the subject invention and the ViSiGi® 3D device. The same line is produced by the Siren SGT device

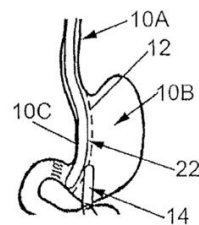
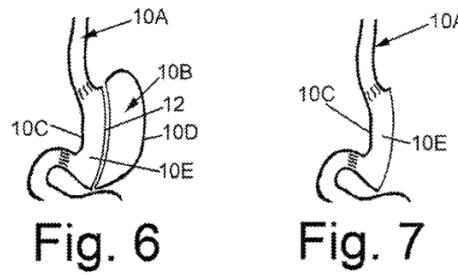


Fig. 5

|   |   |
|---|---|
|   |   |
| <p>c) laparoscopically sealing the patient's stomach from the outside of the patient's stomach along a seal line, said seal line being adjacent said visually perceptible delineation line.</p> | <p>During use of the Siren SGT device for sizing the stomach a portion of the patient's stomach is sealed, e.g., stapled, along the delineation line to form a sealed residual stomach portion like shown in Figs. 6 and 7 of the subject patent reproduced below.</p> <div data-bbox="812 588 1266 861">  <p>Fig. 6      Fig. 7</p> </div> <p>See Exhibit A where the SIREN SGT is used in gastric sleeve formation serving as a sizing guide; See Exhibit C (page 1 of 1, page 1, wherein the SIREN SGT is used for gastric sleeve formation by serving as a sizing guide). See also Exhibit D ('957 Patent-Claim 5).</p> |

59. Defendant has induced infringement of the '415 Patent at least because, with knowledge of the '415 Patent, it intentionally and actively induced end users of the Infringing Product (through instructions, and otherwise) to use it in a manner that infringes the '415 Patent with specific intent that they do so.
60. Defendant has contributed to infringement of the '415 Patent at least by selling the Infringing Product, which has no substantial use other than an infringing use as a method of sizing for a bariatric procedure.
61. Defendant's infringements of the '415 Patent were, and continue to be, willful and deliberate.

62. The Plaintiffs have been damaged by Defendant's infringing activities, and they will continue to be irreparably injured unless the infringing activities are enjoined by this Court.

### **PRAYER FOR RELIEF**

**WHEREFORE**, the Plaintiffs pray for judgment against Defendant as follows:


- A. A finding that Defendant has directly infringed one or more claims of each of the Patents under 35 U.S.C. § 271(a).
- B. A finding that Defendant has induced infringement of one or more claims of each of the Patents under 35 U.S.C. § 271(b).
- C. A finding that Defendant has contributed to the infringement of one or more claims of each of the Patents under 35 U.S.C. § 271(c).
- D. Preliminary and permanent injunctive relief enjoining Defendant and its officers, directors, managers, employees, affiliates, agents, representatives, parents, subsidiaries, successors, assigns, those in privity with them, and all others aiding, abetting, or acting in concert or active participation therewith, from: (1) making, using, selling, offering to sell, or importing into the U.S. any device covered by any of the Patents; or (2) otherwise directly or indirectly infringing any of the Patents.
- E. Compensatory damages, not less than a reasonable royalty under 35 U.S.C. § 284.
- F. Treble damages under 35 U.S.C. § 284.
- G. An order that Defendant account to the Plaintiffs for all sales, revenues, and profits derived from its infringing activities and that three times those profits be disgorged and paid to the Plaintiffs under 35 U.S.C. § 284.

- H. Attorneys' fees under 35 U.S.C. § 285.
- I. Pre-judgment and post-judgment interest.
- J. Costs of the action.
- K. A permanent and final injunction to enjoin Defendant from any further infringement.
- L. Such other and further relief as allowed at law or in equity that the Court deems to be appropriate.

Respectfully submitted,

CAESAR RIVISE, PC

Dated: June 25, 2025

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